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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,007	12/21/2001	Rudi Grutzmann	LE A 33 846	5920

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EXAMINER
HUI, SAN MING R

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/019,007	Applicant(s) GRUTZMANN ET AL.	
	Examiner San-ming Hui	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3,6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This application is a 371 of PCT /EP00/05410, filed June 13, 2000.

Applicant's election of the invention of Group I in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The claims have been examined herein to the extent they read on the elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for MTP inhibitors recited in claim 1, does not reasonably provide enablement for other suitable MTP inhibitor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In the instant case, the specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required

undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that define suitable "MTP inhibitors". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of "MTP inhibitors" examples, namely the ones recited in claim 1, are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on **all** "MTP inhibitors", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "R^1 and R^2, including ..." recited in claim 1 renders the claims indefinite as to what moieties or substituents are encompassed by the claims.

The expression "R^3 and R^4, including ..." recited in claim 1 renders the claims indefinite as to what moieties or substituents are encompassed by the claims.

The term "its part" recited in claim 1, in page 2 of the amendments filed December 21, 2001, is not clear as to which part it is referred to.

The expression "cardiovascular diseases are associated with metabolic diseases or deficits" in claim 2 renders the claims indefinite because it is not clear what association between the cardiovascular disease and the metabolic diseases or deficits. Therefore, it is not clear what cardiovascular diseases are encompassed by the claims.

The expression "optionally associated with" in claim 4 renders the claims indefinite because it is not clear how a secondary disorder being "optionally associated with" a disorder.

The expression "if appropriate" recited in claims 9 and 12 renders the claims indefinite because it is not clear in what situation would be considered "appropriate".

The expression "one or more further suitable components" in claims 9 and 12 renders the claims indefinite because it is not clear what components would be considered "suitable".

Claim 10 contains the trademark/trade name ZD4522. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a HMG-CoA reductase inhibitor and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al. (US Patent 5,684,014 from the IDS received August 12, 2002) and PDR (PDR, 51st ed., 1997, page 770-774).

Muller et al. teaches the compounds of formula (AI) are useful as treating artherosclerosis (See claim 11). Muller et al. teaches the compounds of formula (AI) are useful to be formulated into a pharmaceutical composition with pharmaceutical acceptable diluent (See claim 10). Muller et al. teaches the specific species of compound (AI) (See col. 93-94, example 106; also col. 115-116, example 175).

PDR teaches pravastatin, a HMG-CoA reductase inhibitor, is useful in treating hypercholesterolemia and artherosclerosis (See page 771-772, Indications Section).

The references do not expressly teach the method of treating cardiovascular diseases employing compounds of formula (A1) herein, especially the specific compounds recited in claims 6-8, 10, and 11, in combination of HMG-CoA reductase inhibitors. The references do not expressly teach a composition comprising compounds of formula (A1) herein in combination of HMG-CoA reductase inhibitors and the method of preparation thereof.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employing compounds of formula (A1) herein, especially the specific compounds recited in claims6-8, 10, and 11, in combination of pravastatin in the method of treating cardiovascular diseases. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate pravastatin into a composition of Muller.

One of ordinary skill in the art would have been motivated to employing compounds of formula (A1) herein, especially the specific compounds recited in claims6-8, 10, and 11, in combination of pravastatin in the method of treating

cardiovascular diseases. The compounds of formula (A1) are known to be useful as treating cardiovascular diseases, such as artherosclerosis. Pravastatin is also known to be useful as treating artherosclerosis. It flows logically to combine the two agents together in a method useful for the treatment of artherosclerosis since both agents are known to be useful to treat artherosclerosis individually (See *In re Kerkhoven* 205 USPQ 1069).

One of ordinary skill in the art would have been motivated to incorporate pravastatin into a composition of Muller. Combining pravastatin and the composition of Muller, which are known to be useful to treat artherosclerosis individually, into a single composition useful for the very same purpose is *prima facie* obvious (See *In re Kerkhoven* 205 USPQ 1069).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
Patent Examiner
Art Unit 1617
July 23, 2003